

Categories Eligible for Exempt Certification

Brief description of categories from 45CFR46.101(b)

1. Typical educational practices
2. Educational tests, surveys, interviews, or observation of public behavior (non-sensitive, no identifiers)
3. Research with elected public officials, appointed public officials, candidates for public office
4. Existing data, documents pathological specimens, if publicly available or unidentifiable
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

LIMITATIONS:

1. Research involving children are **NOT** exempt.
2. Research involving the collection or study of existing data, documents, records, specimens **if and only if** the sources are publicly available **or** the investigator records the information in such a way that the subjects cannot be identified directly or through identifiers linked to the subjects. Note: Even a brief recording of identifiers or codes disqualifies the exemption.
3. State or local laws may be more stringent than federal laws; the more stringent laws apply.
4. Foreign customs or laws must be respected and may not allow all or any exemption categories. The more stringent protections apply.

Full text from:

45CFR46.101(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) **Research conducted in established or commonly accepted educational settings, involving normal educational practices**, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:** (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:** (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii)

federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.